

REMARKS

This responds to the Advisory Office Action dated March 31, 2005.

Features of the Invention

The ligator and anoscope system of this invention provides access to the locations of multiple internal hemorrhoids and simultaneously supplies multiple rubber bands for ligation of multiple hemorrhoids, without necessitating multiple retractions and reinsertions of the ligator and the anoscope. (Specification, page 2, lines 27-30.) The size and positions of the apertures of the cylinder makes it possible to possible to grade the sizes of the hemorrhoids. (Specification, page 11, lines 21-29.)

Applicant's anoscope is utilized to expose all three internal hemorrhoids simultaneously, without having to rotate or remove and re-insert the anoscope.

The apertures of the anoscope are located at the three, seven, and eleven o'clock positions, which are the normal anatomic locations of internal hemorrhoids in man in the supine position. Thus, the anoscope is configured to expose all three internal hemorrhoids simultaneously. In this respect, having once inserted the anoscope, all three internal hemorrhoid locations are accessible by virtue of the location of the lateral apertures in the anoscope. Thus, discomfort from repeated insertions of the anoscope and its ligator are minimized. (Specification, pages 4, 5, lines 20-4.)

In man, the three internal hemorrhoids are located at fairly constant locations within the anal canal: left lateral, right anterior, and right posterior positions. These positions are equivalent to the three, seven and eleven o'clock locations with the patient in the supine position. Other prior art anoscopes generally are configured to either expose only one hemorrhoid location at a time or are configured with a plurality of apertures that are not oriented in accordance with the hemorrhoid positions. When using an anoscope having only one aperture, the placement of the anoscope must be precise and movement to expose other hemorrhoids requires the retraction and reinsertion of the anoscope. For anoscopes having a plurality of apertures, careful placement is also required to expose as many of the multiple hemorrhoids as possible. The imprecise placement of the prior art anoscopes requires retraction and reinsertion or adjustment of the device internally, both of which are time consuming and result in discomfort to the patient. (Specification, page 10, lines 1-10.)

A handle 51 extends from the anoscope and extends at an angle away from the longitudinal axis of the anoscope. The handle 51 is positioned at a certain orientation with respect to the apertures of the cylinder and provides a means of knowing the orientation of the apertures when they are hidden for view, as when the anoscope is inserted in the anal canal.

The location of the handle 51 in relation to the anoscope 50 may be in the twelve o'clock or six o'clock positions in order to assure proper positioning of the apertures of the anoscope to the corresponding hemorrhoid locations in man. When the handle is configured in the twelve o'clock position relative to the anoscope 50, the apertures 59A, 59B and 59C of the anoscope 50 are correctly oriented in relation to the internal hemorrhoids for a patient in the prone position. Alternatively, when handle 51 is completely in the six o'clock position, the apertures 59A, 59B and 59C of the anoscope 50 are correctly oriented in relation to the internal hemorrhoids for a patient in the supine position. (Specification, page 11, lines 1-16.)

Claim Rejections - 35 U.S.C. § 103

Claims 26-35, 55-63, 65-74, 76 and 77 were rejected under § 103(a) as being unpatentable over Watson, Jr., et al. (5,788,715) in view of Bayer (6,126,594), and further in view of Bidoia (5,203,863).

The rejection indicates that Watson, Jr., et al. teaches the system for ligation of internal hemorrhoids but no anoscope or loading cone is disclosed, and Bayer teaches the anoscope, and Bidoia discloses the loading mechanism that allows multiple rubber bands to be placed in the cylinder of Watson.

Bayer discloses an anoscope that does not have its openings properly oriented for revealing the hemorrhoids simultaneously. The openings of Bayer are not oriented at the three o'clock, seven o'clock, and eleven o'clock positions, as described. Accordingly, it appears that the Bayer anoscope would have to be repositioned so as to expose one hemorrhoid to the next. This would likely require withdrawing the anoscope, reorienting the anoscope and then reinserting the anoscope, to the discomfort of the patient.

Claim 26 describes the anoscope as follows:

--- wherein the anoscope is configured with an elongated a hollow cylinder having a distal end for insertion in an anal canal and a proximal end for positioning at the entrance of the anal canal with three multiple apertures formed about the hollow cylinder and extending from said distal end along approximately one-half the length of the cylinder at positions about the hollow cylinder for simultaneously exposing hemorrhoids in the anal canal at the normal anatomic locations of the hemorrhoids in a patient without repositioning the anoscope and permitting simultaneous access through said apertures to the normal locations for internal hemorrhoids of the anal canal, and presenting the non-apertured portion of the cylinder to the entrance to the anal canal;

a handle mounted to said cylinder at a predetermined position with respect to said apertures such that by orienting said handle with respect to the patient the apertures are oriented at the anatomical positions of hemorrhoids of the patient, ---.

Bayer does not teach this. The other prior art of record and the prior art known to applicant does not teach this. Accordingly, claim 26 and its dependent claims should be in condition for allowance.

Claim 27 more specifically identifies the orientation of the apertures.

Claims 28 –35 depend from independent claim 26 and include all the limitations thereof. Accordingly, these dependent claims should be in condition for allowance.

Independent claim 55 includes:

--- said apertures being spaced apart about said cylinder to be positionable at the three o'clock, seven o'clock and eleven o'clock positions about the cylinder when inserted in the anal canal with the patient in the supine position, and said lateral apertures each being one-sixth of the circumference of the cylinder such that the sizes of the hemorrhoids can be visually graded by the observer by the degree of extension of the hemorrhoids from outside the cylinder through the apertures of the anoscope

The applied references do not disclose the above noted features. The anoscope as described in claim 55 is constructed differently from the Bayer anoscope and provides an improved result. Accordingly, claim 55 should be in condition for allowance.

Dependent claims 56-65 refer back to and include the limitations of independent claim 55 and should be in condition for the same reasons.

Independent claim 66 includes:

-- said apertures being formed at a predetermined sized to observe the size of the hemorrhoids by the extension of the hemorrhoids from outside said cylinder and through the apertures, and
visual means at said proximal end of said cylinder for visually rotatively orienting said anoscope with the apertures of said cylinder oriented in the anal canal with the apertures in registration with the hemorrhoid positions of man.

The above noted features of the invention are not disclosed or suggested by Bayer. Also, while Bayer has multiple apertures, they are not disclosed as being in the locations specifically described in the claims of this application. Bayer does state that his anoscope provides convenient access to any number of hemorrhoids at any angle. (Column 1, lines 62-67.) However, this does not provide simultaneous access as described by applicant and as set forth in the claims of the application. Bayer also states that the spacing of the strips that form the openings may be variable, if desired. (Column 3, lines 1-7.) However, Bayer does not disclose applicant's concept of an anoscope with properly spaced openings for achieving applicant's result of simultaneous and exclusive access to the hemorrhoids.

Dependent claim 69 has the feature of the handle functioning as the visual means for visually rotatively orienting the anoscope. Again, this is not disclosed or suggested by Bayer.

Dependent claim 70 describes the features of the apertures not extending more than halfway along the length of the *cylinder* to expose only internal hemorrhoids in the anal canal. Again, not disclosed in Bayer.

Dependent claim 75 describes the orientation of the apertures when the patient is in the inverted or prone position.

Independent claim 77 sets forth:

said cylinder defining three lateral apertures opening about one-half the distance from the distal end of said cylinder toward the proximal end of said cylinder, said three apertures being spaced radially apart about said cylinder to register with the internal hemorrhoids in the normal anatomic location of man of the patient,

a handle extending radially away from the proximal end of the cylinder at predetermined angle with respect to the apertures of the cylinder such that when

the cylinder is inserted in the anal canal of the patient and the handle is oriented at a predetermined attitude with respect to the patient the apertures of the cylinder register with the internal hemorrhoids of the patient.

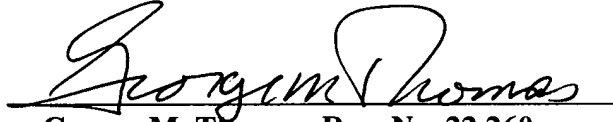
Again, these features of claim 77 are not suggested, taught, or made obvious by the cited references.

The statement in the advisory action says that Bayer meets the requirements of the apertures being half way along the length of the anoscope. However, the claims now clearly state that the apertures extend approximately half way along the length of the *cylinder*, not the *anoscope*.

Bayer does not identify hemorrhoids in the proper anatomical locations and does not match his anoscope to those locations.

Applicant requests favorable reconsideration of the application.

Respectfully submitted,

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